Independent Verification & Validation Facility	**Internal Quality Audits**	**IVV 17** **Revision: H** **Effective Date:** **March 2003**

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APPROVAL SIGNATURES		DATE
Greg Blaney (original signature on file)	QMS Management Representative	03/04/03

REVISION HISTORY			
Rev No.	Description of Change	Author	Effective Date
Basic	Initial Release	John Griggs IT/204	08/26/98
A	Format Changes	John Griggs IT/204	09/11/98
B	Consolidation of forms	John Griggs IT/204	01/28/99
C	References to Ames Quality Manual replaced with references to IV&V Facility Quality Manual Updated Section 6.4	John Griggs IT/204	09/10/99
D	Format and Number changes; Delete Reference to Ames Research Center	Griggs	12/06/00
E	Remove reference to Ames, minor changes to Audit procedure	Griggs	4/19/01
F	Response to audit finding 2001-C-77, define “immediate”	Griggs	8/29/01
G	Clarify use of Form IVV 1005; Formatting and numbering corrections	Griggs	10/21/02
H	Clarify criteria for internal audit content determination	Griggs	03/05/03

REFERENCE DOCUMENTS	
Document Number	Document Title
IVV QM	IV&V Facility Quality Manual
IVV 14	Corrective and Preventive Action
IVV 16	Control of Quality Records
IVV 18	Training

1.0 Purpose

This procedure defines how audits of the IV&V Quality Management System (QMS) shall be planned, scheduled and conducted, and their results documented and reported to management to ensure that:

1.1 The QMS effectively implements the IV&V Quality Policy and conforms to the IV&V Facility Quality Manual (IVV QM).

1.2 Documented plans, procedures, and work instructions reflect the organization's current operations, responsibilities, and products.

1.3 Personnel, processes, products, and services comply with documented requirements.

1.4 Corrective and preventive actions are systematically identified to improve process and QMS performance.

2.0 Scope

This procedure applies to the IV&V Facility Quality Management System whose processes directly affect the quality of the products and services delivered to customers.

3.0 Definitions and Acronyms

3.1 Audit Manager - The person(s) responsible for managing the internal quality audit program.

3.2 Commendation - A commendation is written to cite an exemplary system or process of the auditee.

3.3 Customer - The purchaser, user, or recipient of a product or service provided by the IV&V Facility.

3.4 Nonconformance

A lack of compliance to a specified process or procedure associated with the Facility's Quality Management System, a nonconforming product, or a deficiency in the Quality Management System itself. For the purposes of this procedure, nonconformances will be categorized into three levels of severity.

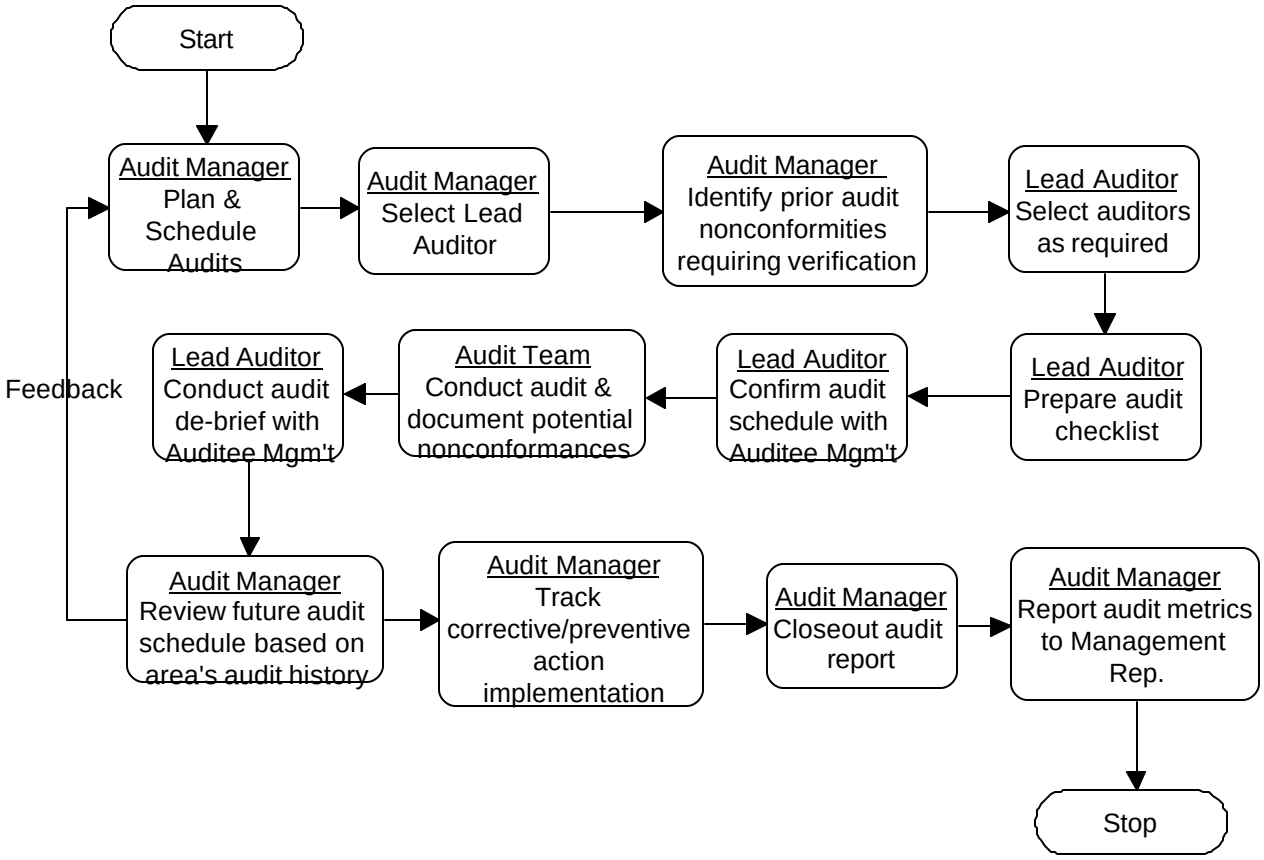
3.4.1 Major - a quality system deficiency exists; a nonconforming product is issued and the nonconformity has a significant effect on customer success, safety or resources; lack of documented procedures, documented procedures are not being implemented consistently, or a series of minor nonconformities indicated an overall quality system weakness which has an adverse effect upon overall product quality.

3.4.2 Minor - a defined system exists with an acceptable level of implementation, however, there are minor discrepancies or lapses in discipline; a nonconforming product is issued and the nonconformity has little or no effect on the customer

3.4.3 Observation - an issue noted by an auditor that may lead to a nonconformanity if not corrected, a suggestion to improve a process, or editorial corrections to a procedure (i.e. typing errors, misspelling, etc.).

3.5 Recommendation - A proposal to improve the effectiveness of operating practices.

4.0 Flow Chart



5.0 Responsibilities

5.1 The IV&V Facility Director shall:

5.1.1 Assign an Audit Manager to plan, schedule, and manage the IV&V Facility Internal Audit process.

5.1.2 Ensure the Audit Manager has attended an Accredited Lead Auditor Class of the Registrar Accreditation Board.

5.2 The Audit Manager shall perform the following functions:

5.2.1 Audit Preparation

5.2.1.1 Identify auditor training needs in accordance with IVV 18, and ensure:

- all auditors receive formal training in audit methods and objectives.
- Lead Auditor candidates attend an Accredited Lead Auditor class and/or possess sufficient audit experience or on-the-job training as determined by the Audit Manager.

5.2.1.2 Develop the Center's audit schedule and secure the review and approval of the IV&V Facility Director or designee, and ensure:

- the audit schedule covers approximately 12 months.
- audits cover all aspects of the Quality Management System during that 12-month period.
- the depth and frequency of each audit is based on the prior audit history and operational status of the area to be audited, as well as status and importance of the process within the IV&V management system.

5.2.1.3 Assign a sequential audit tracking number to each planned audit.

5.2.1.4 For each area to be audited, select a Lead Auditor and team who are not directly responsible for performance of the activity being audited.

5.2.1.5 Ensure audits are performed in accordance with the approved audit schedule.

5.2.1.6 Reconcile any disagreements between Lead Auditors and audited organizations.

5.2.2 Audit Conclusion and Documentation

5.2.2.1 Review audit reports for clarity and completeness.

5.2.2.2 Distribute audit reports to affected management.

5.2.2.3 Compile and report internal audit metrics to management in accordance with the Process Metrics section of this procedure.

5.2.2.4 Authorize closure of Audit Reports only after associated corrective and preventive actions are opened in the CAR/PAR system.

5.2.2.5 Ensure records are managed in accordance with the Records section of this procedure.

5.3 Each Lead Auditor shall:

5.3.1 Select additional auditors if required by the depth and duration of the planned audit.

5.3.2 Confirm specific audit dates and times with area management.

5.3.3 Prepare audit checklist by either:

5.3.3.1 selecting appropriate sections from a suitable checklist, or

5.3.3.2 preparing a tailored audit checklist based on prior audit results and specific process or product requirements.

5.3.4 Obtain and review all pertinent documents related to the area being audited.

5.3.5 Conduct opening meetings and post-audit briefings with area management.

5.3.6 Reconcile any disagreements between auditors and audited organizations, or, when necessary, submit disagreements to Audit Manager for reconciliation.

5.3.7 Review any corrections and preventive actions; amend these as necessary to accurately reflect audit Observations.

5.3.8 Within approximately 2 weeks of audit completion, provide the Audit Report and any corrective and preventive actions to the Audit Manager for review.

5.4 Each Auditor and Lead Auditor shall:

5.4.1 Audit the assigned areas.

5.4.2 Review the policies, plans, procedures, and work instructions for the area to be audited; determine whether these adequately address all applicable requirements in the Quality Manual.

5.4.3 Interview appropriate personnel and determine whether their actual practices conform to the requirements of the documented policies, plans, procedures, and work instructions.

5.4.4 Document any Findings.

5.4.5 After the audit, compile all Findings and categorize them as either major/minor Nonconformities, Observations, or Commendations using the IV&V Form 1005.

5.5 Each Audited Organization's Management shall:

5.5.1 Inform area personnel of the time and scope of the audit.

5.5.2 Assign a knowledgeable guide to accompany each auditor.

5.5.3 Provide timely access to processes, products, and documentation needed by the auditor.

5.5.4 Ensure all personnel cooperate with the auditor.

5.5.5 Assist the Lead Auditor in clarifying any issues that come up during the audit or at the post-audit briefing.

5.5.6 Review and understand the Audit Report.

5.5.7 Respond to any corrective or preventive actions in accordance with IVV 14.

6.0 Procedure

6.1 The IV&V Facility audit schedule will be submitted to the Facility management for signature. The schedule will be maintained as a 12 month rolling schedule, updated quarterly.

6.2 The Facility will normally use a suitable audit checklist content, at the discretion of the individual auditor. Open past audit findings and Corrective Action Requests will be factored into the audit planning.

6.3 Individual audits will be tracked by unique identifiers (numbers). Nonconformance reports will be numbered sequentially using the audit number-sequence number.

6.4 Audit findings will be documented on IVV Form 1005, Finding Report. Post audit, the findings will be documented and tracked in the Corrective Action system as nonconformances, and will be acted upon as follows:

- A major finding shall result in immediate* action.
- A minor finding may require immediate action.
- An observation does not require immediate action.

*"Immediate" action: Finding requires completion of the corrective action, or submission and approval of a Corrective Action Plan, within 2 weeks (see IVV 14).

Tracking and resolution of the action is controlled by the IVV 14, Corrective and Preventive Action, section 5.4.4.

7.0 Metrics

Approximately quarterly, the Audit Manager shall report appropriate internal quality audit metrics to the IV&V Facility Management Representative. Appropriate metrics could include, as a minimum, rolling 12-month trends of the following:

7.1 Percent of audits conducted more than 30 days later than originally scheduled.

7.2 Trend analysis of findings (C/PARs) identified during audits.

7.3 Percent of findings (C/PARs) open from previous audits.

8.0 Records

The internal audit process will generate the following records and will be filed in accordance with IVV 16:

Document Name and Identification Number	User Responsible for Record Retention	Retention Requirement	Location
Audit Schedule	Audit Manager	3 years (min)	Audit Folder/electronic file
Audit Report	Audit Manager	3 years after closure	Audit Folder/electronic file
IVV Form 1005 (Finding Report)**	Audit Manager	3 years after closure	Audit Folder/electronic file

**: Finding reports are used primarily for audit reporting; may also be used to log a CAR/PAR (see IVV 14) if Trackwise is not available.